REMARKS

Claims 15-30 have been rejected as follows:

(1) under 35 U.S.C. § 103(a) over Richter et al. (USP 5,705,518) in view of Nakajima et al. (WO 94/11100);

(2) under 35 U.S.C. § 112, second paragraph; and

(3) under obviousness-type double patenting over claims 1-12 of USP 6,074,666.

Applicants respectfully traverse these rejections and address them in order below.

Rejection under 35 U.S.C. § 103(a)

Claims 15-30 have been rejected under 35 U.S.C. § 103(a) over Richter et al. over Richter et al. (USP 5,705,518) in view of Nakajima et al. (WO 94/11100).

Applicants respectfully traverse because neither document teaches or suggests liposomes which are "fast breaking and rapidly release" photosensitizer into the bloodstream upon *in vivo* administration as required by the claims. As such, no *prima facie* case of obviousness has been presented because the cited documents, alone or in combination, do not teach the recited limitation in claims 15-30. See MPEP 2143.03 and the case law cited therein.

The Examiner's attention is also directed to the standard that a "claim limitation which is considered indefinite *cannot be disregarded*" (italics added, see MPEP 2143.03). Thus the above quoted limitation from the claims, which have been rejected for indefiniteness as discussed below, must still be considered before rejecting the claims based on prior art.

But because the art fails to teach or suggest the limitation, no *prima facie* case of obviousness has been presented and the instant rejection may be properly withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 15-30 have been rejected under 35 U.S.C. § 112, second paragraph.

As an initial matter, the Examiner's assertion that the claims are not limited to the "improved working properties regarded by the applicants to be critical" is not understood. But because this assertion is followed by a reference to specific examples of the application, Applicants are of the belief that the Examiner means that the claims are not limited by the recitation of specific components and amounts which result in the "fast breaking and rapidly release" characteristic.

This is specifically, and respectfully, traversed with respect to claims 19 and 26-29, which are directed to specific components and amounts. Instant claims 19, 26 & 27, and 29 are similar to claims 1, 10 & 11, and 12 of USP 6,074,666 (which is the basis for the double patenting rejection discussed below). As such, at least claims 19 and 26-29 should not be subject to the above concern by the Examiner.

The Examiner also asserts that the terms "fast breaking" and "rapidly release" are vague and do not define values which would correspond to data of the specification. Applicants respectfully traverse because these terms **are** reflective of the data of the specification. The Examiner's attention is respectfully directed to Example 3 and the associated tables on pages 24 and 25 of the specification, where the data of the Example are expressly described as *demonstrating* the fast breaking nature of the liposomal formulations of the invention. Thus the

terms do reflect the necessary components, amounts and values characteristic of the claimed liposomal formulations.

To the extent that the instant rejection may be based on a view of the terms "fast breaking" and "rapidly release" as functional in nature (or describing an attribute), the Examiner's attention is respectfully directed to the standard that "[t]here is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper." See MPEP 2173.05(g) and the case law cited therein. MPEP 2173.05(g) states that functional limitations should be evaluated and considered "for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used."

In the instant application, the terms "fast breaking" and "rapidly release" would be viewed by the ordinary artisan in light of the specification at least on page 9, first three complete sentences. As stated therein, "fast breaking" liposomes of the invention are those which are "stable *in vitro* but when administered *in vivo*, the photosensitizer is rapidly released into the bloodstream where it associates with serum lipoproteins." The terms would thus be clear and definite to the ordinary artisan (as required at MPEP 2173.05(g)).

Applicants respectfully submit that the instant rejection is misplaced, especially with respect to claims 19 and 26-29 (which recite specific components and amounts of the claimed liposomal formulations), and request its withdrawal.

Alternatively, and in the event that the rejection may be maintained, Applicants request an indication of whether introduction of the above quoted language from page 9 of the application may advance prosecution with respect to the instant rejection.

Rejection under double patenting

Claims 15-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of USP 6,074,666.

Applicants are prepared to submit a terminal disclaimer to obviate the rejection and thus respectfully ask that the instant rejection be held in abeyance until the claims are found to be otherwise allowable.

Conclusion

In light of the above discussion, Applicants respectfully submit that the claims are allowable, and passage of the application to issue is urged. The Examiner is welcome to contact the undersigned to resolve any residual issues, such as the submission of a terminal disclaimer, or if further discussions may be thought useful.

In the event that the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **273012008102**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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